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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/316,048	05/21/1999	LUC DESGROSEILLERS	10875.77	7290

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EXAMINER

SHUKLA, RAM R

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 09/10/2002

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/316,048

Applicant(s)

DESGROSEILLERS ET AL.

Examiner

Ram Shukla

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-8 and 24-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-8 and 24-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *detailed action*.

Art Unit: 1632

DETAILED ACTION

1. Amendment and response filed 6-26-02 have been received.
2. Claims 1-3, 9-23 have been cancelled.
3. New claims 26-29 have been entered.
4. It is noted that applicants have indicated claim 25 as amended however it is not clear what has been amended. While applicants have provided a marked up version of the amendment, there is no different between the amended and the previous version of the claim 25.
5. Claims 4-8 and 24-29 are instantly under consideration.
6. Applicants' submission of the foreign priority document, a certified copy of the application (#2,238,656) is acknowledged.

Specification

Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

It is noted that in the office action of 5-23-01, specification was objected to for non-compliance with sequence rules. While applicants identified the nucleotide sequences disclosed on page 42-43 and 45, there is no evidence that the nucleotide sequences disclosed in figures were identified by sequence identifiers.

It is reiterated that For compliance with sequence rules, it is necessary to include all the sequences in the "Sequence Listing" and identify them with SEQ ID NO. In general, any sequence that is disclosed and/or claimed as a sequence, i.e., as a string of particular bases or amino acids, and that otherwise meets the criteria of 37 CFR 1.821(a), must be set forth in the "Sequence Listing." (see MPEP 2422.03).

For the response to this office action to be complete, Applicants are required to comply with the Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1632

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 4-8 and 24-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for (i) an isolated nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO 1, 3, 5, 7, and 9, (ii) an isolated nucleic acid encoding the amino acid sequence of SEQ ID NO 6, SEQ ID NO 11, SEQ ID NO 2, amino acid residues 2-577 of SEQ ID NO 6 and amino acid residues 2-487 of SEQ ID NO 11 and (iii) a nucleic acid complimentary to the full length nucleic acids of (i)-(iii), a recombinant vector comprising the isolated nucleic acid, a method of making a recombinant host cell comprising the isolated nucleic acid, a host comprising the nucleic acid, and a method of making the polypeptide encoded by the nucleic acid, does not reasonably provide enablement for a nucleic acid encoding a Staufen polypeptide comprising amino acids 82-577 or 83-577 of SEQ ID NO 6 or other recited embodiments for reasons of record set forth in the previous office action of 8-23-01, 2-21-02 and as discussed below. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Response to Arguments

Applicant's arguments filed 6-26-02 have been fully considered but they are not persuasive. In response to the rejection of the fragment 82-577, applicants have argued that the interpretation of in the office action is incorrect. While applicants arguments and interpretation is well taken, the specification nowhere discloses what is the nexus between SEQ ID NO 6 with figure 1b. Accordingly, an artisan would not be able to interpret SEQ ID NO 6 as the applicants have interpreted in their arguments. Applicants are requested to provide where in the specification the nexus between the figure and SEQ IDs has been disclosed. It is suggested that to clarify the issue, applicants may use the amino acid numbers of SEQ ID that corresponds to figure 1b. It is further noted that if the claim is issued,

Art Unit: 1632

an artisan would not have access to the interpretation presented in the arguments and therefore would not have known whether fragment 82-577 of SEQ ID NO 6 contained the domain for RNA binding. As noted in the previous office action, it is reiterated that it is unclear, based on the teachings of the specification, whether the fragment 82-577 would bind to dsRNA or would have any other activity attributed to full length SEQ ID NO 6. In other words, it is unclear whether the fragment would have the function of the protein of SEQ ID NO 6. Rejection of claim 19 is moot in view of the cancellation of the claim, however issues of rejection discussed in the rejection of this claim as applicable to other pending claims are maintained. Applicants have argued that claim 25 has been included in the rejection by mistake, however, it is not so since claim 25d encompasses conservative substitutions, it was included in the rejection is maintained for reasons of record set forth in the previous office action of 2-21-02 (see last paragraph on page 4 continued on page 5). It is noted that while that the rejection pertaining to claim 19 are relevant to claim 25d and therefore the rejection is maintained. It is noted that applicants did not address issues of rejection based on sound scientific reasoning on pages 4 and 5 of the previous office action of 2-22-02. It is further noted that applicants have repeatedly used the statement that that procedures are conventional in the art without providing any evidence. Applicants are reminded that applicants argument alone cannot take place of evidence lacking in the record (see *In re Scarbrough* 182 USPQ, (CCPA) 1979).

Next, regarding the rejection of polynucleotides that encode protein that is 95% identical to recited polypeptide, applicants have argued that the claims 4 and 24 meet the requirement because they teach an assay which will identify other nucleic acid molecules which encode staufen. Applicants further cite examples 11 and 12 for teaching the assay. Applicants also argue that procedures for making variants of specific sequences having 95% identity and retaining their activity are conventional in the art and that the genus of proteins claimed don not have a substantial variation since they all possess the recited activity. Again, while it is agreed that the specification teaches assay to check activity of a protein, the issue as discussed on pages 3 and 4 is: how would an artisan decide which 5% amino

Art Unit: 1632

acids to alter without altering the activity. For example, SEQ ID NO 6 is a 577 amino acid protein and 5% of this would be 28 amino acids and the specification does not teach which 28 amino acids to alter and still maintain the biological activity of the full length protein. It is noted that while it is routine in the art to alter one or two amino acids in a certain motifs, there is no evidence of record that it was routine in the art to alter 5% amino acids in a protein. Applicants are advised to provide any such evidence to support their assertion that it was routine in the art to alter 5% amino acids in a protein.

It is further noted that applicants have argued both the written description and enablement rejection of claim 4 which has confused the issues. Regarding the rejection of polynucleotides that encode protein that is 95% identical to recited polypeptide, applicants have cited written description guidelines example of a product by function claim reciting a protein having a specific sequence or variants that are at least 95% identical to this specific function and have a specific function. Applicants have listed four points in the last paragraph on page 8 saying as to what is concluded by USPTO and that USPTO concluded that claims would meet the written description requirement. It is not clear whether applicants are arguing written description argument or enablement rejection. It is noted that claim 4 was not rejected for written description.

In summary, it is reiterated that in view of the breadth of the claims and the lack of guidance provided by the specification as well as the unpredictability of the art, one of ordinary skill in the art at the time of the invention would have required an undue amount of experimentation to make and use claimed polynucleotides commensurate with the scope of the claimed invention and therefore, limiting the scope of the claimed invention to (i) an isolated nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO 1, 3, 5, 7, and 9, (ii) an isolated nucleic acid encoding the amino acid sequence of SEQ ID NO 6, SEQ ID NO 11, SEQ ID NO 2, amino acid residues 2-577 of SEQ ID NO 6 and amino acid residues 2-487 of SEQ ID NO 11 and (iii) a nucleic acid complimentary to the full length nucleic acids of (i)-(iii), a recombinant vector comprising the isolated nucleic acid, a method of making a recombinant host cell comprising the isolated nucleic acid, a host

Art Unit: 1632

comprising the nucleic acid, and a method of making the polypeptide encoded by the nucleic acid is proper.

9. Claim 4 remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record set forth in the previous office action of 8-23-01, 2-21-02 and as discussed below.

Response to Arguments

Applicant's arguments filed 6-26-02 have been fully considered but they are not persuasive. Applicants are asserting that SEQ ID NO 27 is not a 27 amino acid polypeptide but a 705 amino acid sequence. While an inadvertent error in describing SEQ ID NO 27 as a 27 amino acid polypeptide is acknowledged, it is reiterated that SEQ ID NO 27 is not a 705 amino acid sequence. It seems like applicants have made this statement and assertion without looking at the sequence listing. Applicants attention is drawn to last two pages of the sequence listing. At the end of last but one page the sequence listing discloses SEQ ID NO 27 as follows:

<210>27

<211>40

<213> unknown organism

<220>

<223> Description of unknown organism: unknown

<400> 40

sequence of amino acid follows.

Art Unit: 1632

It is not clear as to on what basis applicants are asserting that the SEQ ID NO 27 has 705 amino acid sequence and that it is a C.elegans sequence. Accordingly, the rejection of claim 4 is maintained.

7. No claim is allowed.

8. The nucleic acid sequences of SEQ ID NO 1, 3, 5, 7, and 9 are free of the prior art of record.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

When amending claims, applicants are advised to submit a clean version of each amended claim (without underlining and bracketing) according to § 1.121(c). For instructions, Applicants are referred to <http://www.uspto.gov/web/offices/dcom/olia/aipa/index.htm>.

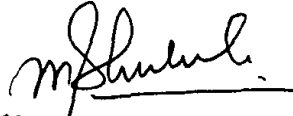
Applicants are also requested to submit a copy of all the pending/under consideration claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on

Art Unit: 1632

(703) 305-4051. The fax phone number for this Group is (703) 308-4242. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Dianiece Jacobs whose telephone number is (703) 305-3388.

Ram R. Shukla, Ph.D.


RAM R. SHUKLA, PH.D
PATENT EXAMINER